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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/099,823	BILLING-MEDEL ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *December 2, 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-29,31,32,34,36,37,43,44 and 50-74* is/are pending in the application.

4a) Of the above claim(s) *17-29,31,32,34,36,37,43 and 44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (*to a provisional application*).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to the papers filed December 2, 2002. Currently, claims 17-29, 31-32, 34-36, 37, 43-44, 50-74 are pending. Claims 17-29, 31-32, 34, 36-37, 43-44 have been withdrawn from consideration. Claims 50-74 have been examined on the merits. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.

2. Any objections and rejections not reiterated below are hereby withdrawn.

3. This action contains new grounds of rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 50-74 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from http://www.uspto.gov/web/menu/utility.pdf]

> "Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A *credible* utility is

assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).

"Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring.

On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a *specific* or *substantial* utility. For example, using transgenic mice as snake food is a utility that is

neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. ' 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, it a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial *asserted* utility would be considered to be met.

"Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

5. The claims drawn to polynucleotides, and method of detecting the polynucleotides in a test sample as defined in the specification as products of a breast tissue gene designated as BS124. The specification teaches the general utility for the invention is detection of the gene product itself in a sample. The specification does not teach a specific utility of the polynucleotides, genes and proteins whereby the invention would be a useful tool for a specific purpose i.e. detection of itself in a sample detects the presence of a disease. The specification also does not provide any teachings as to the function of the encoded protein. The specification suggests that the invention may have substantial utility i.e. as an anti-BS124 antibody useful as a therapeutic agent. However, the specification does not teach the therapy or demonstrate therapeutic

results. Additionally, the specification suggests that the invention may have substantial utility i.e. the gene products may be useful for the diagnosis of breast cancer by using the gene products to detect themselves in a tissue sample by hybridization. However, the specification does demonstrate the diagnostic utility. Specifically, the specification teaches that the claimed gene products detect themselves in cancerous breast tissue. Additionally, the specification teaches that the BS124 was found in non-breast libraries. Similarly, BS124 sequences were observed in normal breast tissue RNAs and breast cancer tissue RNAs. Therefore, the specification does not teach a specific or substantial utility for the invention such that the invention would be useful to detect or treat a disease state. While the utility of gene products has been established in the art, applicants have not demonstrated a specific or substantial utility for the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts that "a claimed invention must have a specific and substantial utility that is credible." The response addresses the credibility criteria. The examiner has not directed any arguments to the credible aspect of utility. The examiner asserts that there is no specific or substantial utility. The response asserts that "BS124 can be used to provide information leading to the detection, diagnosis, staging, monitoring, prognosticating, prevention or treatment of or determining the predisposition to breast cancer." This passage does not provide a substantial utility for the claimed nucleic acids. As provided by the Utility Guidelines, a "substantial utility" is a utility that defines a "real world use." Utilities which require or

constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. As is here, the specification does not provide adequate support for the assertion. The specification fails to provide adequate support for the assertion of diagnosing or prognosing breast cancer based upon BS124. The specification, as discussed above, clearly illustrates that BS124 is expressed in both normal and cancerous tissue. There does not appear to be any difference in expression patterns. Thus, it is unclear how the skilled artisan would be able to use the invention without carrying out further research to reasonably confirm the "real world" use.

The response asserts that the BS124 is a novel polypeptide belonging to the lipocalin family which serve as transfer molecules and provides post filing date support including the reference by Lacazette which was previously considered. As provided in the Office Action mailed September 14, 2000, lipocalin-encoding" was not part of the original specification and disclosure. It is noted that utility is required at the time of filing. Therefore, support for the utility after the filing date of the invention does not illustrate that at the time the invention was made the specification provided how to use the claimed invention. It appears as though applicants may be trying to establish a well-established utility. However, at the time the invention was made, the ordinary artisan would not have been able to use the assignment to the lipocalin family as a well-established utility because the information was not present. Thus, regardless of whether the nucleic acid was later determined to be a member of a family which was not previously known, this information does not support an assertion for well-established utility at the time the invention was made.

Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 50-74 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 50-74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification provides numerous assays and results with regard to detection of "the BS124 probe". It is unclear however, what this probe includes. It is unclear whether this probe is the entire SEQ ID NO: 5 or whether the probe is a smaller fragment of 5, or whether numerous probes were used. Clarification is requested.

The specification teaches "EST's corresponding to the consensus sequence of BS124 were found in 5.9% (2 of 34) of breast tissue libraries (pg 57, lines 21-23). The specification further teaches that EST's corresponding to the consensus sequence of

SEQ ID NO: 5 or fragments thereof were only found in 0.3% of the other non-breast libraries of the database (pg 57, lines 23-25).

The specification teaches that RNA was isolated from breast tissue and from non-breast tissue (pg 59). The specification teaches performing an RNA protection assay (pg 62-64). The specification teaches that the RNA was mixed with labeled probe, however, it is unclear what the sequence of this probe entailed (pg 63, lines 6-8). The gels were imaged and analyzed and quantitation of protected fragment bands was achieved. Results of the assay indicated that four of five of the normal breast tissues had detectable bands, whereas three of the six breast cancer samples had detectable bands. This appears to clearly illustrate that the BS124 nucleic acids is present in both normal and cancerous samples. While it is noted that the quantification of the nucleic acids from the normal samples appeared lower on several samples than the cancerous samples, the BS124 nucleic acid appears in more normal samples than cancerous samples (Table 1, page 64).

The specification teaches Northern Blotting to identify a specific size RNA species. It remains unclear what probe was used in the assay. However, it appears clear that the probe was detected in the normal testis (Figure 3A). From Figure 3B it also appears as though the probe was detected in two of six breast cancer samples.

The specification also describes an RT-PCR assay in which shows a "100 bp BS124-specific PCR amplification product in lanes 3-11, indicating that BS124 mRNA was present in 9 or 10 normal and breast cancer samples tested" (pg 69, lines2-5). Turning to Figure 4A, it is clear that all five of the normal samples contained the BS124

mRNA, however, one of the breast cancer samples did not. The specification also provides that the 100 bp BS124 specific PCR amplification product is observed (faintly) in normal lung sample (Figure 4B). The specification suggests that BS124 is breast specific (pg 69, line 6).

Neither the specification nor the art teaches how to make and use the invention as broadly as claimed. The claims are directed to detecting a polynucleotide indicative of breast cancer. The specification asserts that BS124 is breast specific, however the detection of a BS124 polynucleotide has been identified in testis, normal breast tissue, cancerous breast tissue and normal lung samples using the various assays described. Moreover, with respect to the instant claims drawn to detecting polynucleotides indicative of breast cancer, the specification provides several assays including, RT-PCR assays and RNAase Protection Assays. It is unpredictable for the skilled artisan to detect a polynucleotide indicative of breast cancer using the instant nucleic acids because the instant nucleic acids are not indicative of breast cancer. Based upon the teachings in the specification, the instant nucleic acids are do not appear indicative of breast cancer.

Therefore, the skilled artisan would be unable to use the claimed methods and products.

Response to Arguments

The response traverses the rejection. The response asserts that the BS124 is a novel polypeptide belonging to the lipocalin family which serve as transfer molecules and provides post filing date support including the reference by Lacazette which was

previously considered. As provided in the Office Action mailed September 14, 2000, lipocalin-encoding" was not part of the original specification and disclosure. It is noted that utility is required at the time of filing. Therefore, support for the utility after the filing date of the invention does not illustrate that at the time the invention was made the specification provided how to use the claimed invention.

Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 112- Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 68-69, 74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotides having a sequence selected from the group consisting of SEQ ID NO: 4 and 5 (Claim 69). The claims are also drawn to a composition of matter comprising a polynucleotide selected from the group consisting of SEQ ID NO: 1, 2, 4, 5 (Claims 68, 74).

The specification teaches the polynucleotides consisting of SEQ ID NO: 1-5. The specification teaches a single BS124 consensus polynucleotide, SEQ ID NO: 5, the

sequence of which was assembled from 3 EST clones (SEQ ID NO:1-3) and the fill-length clone (SEQ ID NO: 4) (pg. 57).

Vas-Cath Inc. V. Mahurkar, 19 USPQ2b 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its ennoblement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2b 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...' required a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of specifies have been described by their complete structure. In the instant case, Applicant has defined only a fragment of a nucleic acid sequence. Applicant has not disclosed any genomic DNA sequences and particularly has not disclosed any intron sequences or regulatory sequences. Accordingly,

Applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus.

There is not adequate description of the genus of polynucleotides having SEQ ID NO: 4 or 5 and compositions of matter comprising SEQ ID NO: 1, 2, 4, 5. These claims encompass the full length gene, the full length cDNA molecules which have not been described. Thus, the claims have not provided a representative number of species within the genus claimed.

Response to Arguments

The response does not appear to address the written description rejection. Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 50-59, 70-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A3) Claims 50-59, 70-73 are indefinite over the recitation "a method of detecting a target polynucleotide indicative of breast cancer" because it is unclear whether the claim is drawn to a method of detecting a polynucleotide or whether the claims is directed to a method of detecting breast cancer as a result of detecting the polynucleotide.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (f) he did not himself invent the subject matter sought to be patented.

9. Claims 61-64, 68 are rejected under 35 U.S.C. 102(a) as being anticipated by Incyte LifeSeq™ Database (see specification at page 57, lines 5-10).

As applicants have asserted in the specification, the nucleic acid clones for the sequences of SEQ ID NOS 1-3, (1730294, 1213903, g2185139) were procured from, and therefore known and used by, Incyte Genomics at the time the invention was filed. It is noted that the nucleotide sequence is an inherent property of the nucleic acid clones. Therefore, polynucleotides consisting and comprising SEQ ID NOS 1-3, as well as those that could be produced by either recombinant techniques or synthetic techniques, as well as compositions of matter comprising a polynucleotide of SEQ ID NO 1 or SEQ ID NO: 2 or SEQ ID NO 3 were known and used in the art at the time of filing of the instant application.

10. Claims 61-64, 68 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention.

As applicants have asserted in the specification, the nucleic acid clones for the sequences of SEQ ID NOS 1-3, (1730294, 1213903, g2185139) were procured from, and therefore known and used by, Incyte Genomics at the time the invention was filed. It is noted that the nucleotide sequence is an inherent property of the nucleic acid clones.

11. Claims 61-64, 68 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

As applicants have asserted in the specification, the nucleic acid clones for the sequences of SEQ ID NOS 1-3, (1730294, 1213903, g2185139) were procured from, and therefore known and used by, Incyte Genomics at the time the invention was filed. It is noted that the nucleotide sequence is an inherent property of the nucleic acid clones.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 63-64, 70, 72, 74, 75, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Incyte LifeSeq™ Database (see specification at page 54, line 30, and page 55 lines 9-10), in view of Londos et al (US Patent 5,585,462).

This rejection is directed to the claims in the event that they are drawn merely to detecting polynucleotides, rather than detecting polynucleotides associated with breast cancer, i.e. detecting breast cancer.

Claims 65-67 are drawn to expression systems and cells transfected with such, comprising the nucleic acids of SEQ ID NOS 1-3. As applicants have asserted in the specification, the nucleic acid clones for the sequences of SEQ ID NOS 1-3, (1730294, 1213903, g2185139) were procured from, and therefore known and used by, Incyte Genomics at the time the invention was filed. Although the nucleic acid clones are not specifically taught as procured in a recombinant expression system or cell comprising such, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to construct an expression system comprising one of nucleic acids of SEQ ID NOS 1-3 to express any proteins encoded by such. Such methods were known in the art at the time of the invention as exemplified by the teachings of Londos, which teaches how transfect a cell with nucleic acids for the purposes of expression protein (col. 14, lines 53-col. 15).

Londos further teaches that the DNA can be directly detected using Southern hybridization with probes that hybridize and detect the DNA (see col. 21, lines 45-50) (claim 50). Londos also teaches that sandwich hybridization can be used to detect the DNA where in the assay utilizes a "capture" nucleic acid covalently immobilized to a solid support and a labeled 'signal" nucleic acid in solution which bind to the target DNA (see col. 22, lines 10-30). Londos also teaches using RT-PCR for amplification of RNA sequences (see col. 29, lines 1-2). While Londos does not teach detection of mRNA

using RT-PCR and subsequent hybridization and detection with a probe, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made that mRNA could be detected using RT-PCR to produce cDNA and that the cDNA could be detected with a probe specific for the cDNA sequence. Such amplification and detection methods were readily known and practiced at the time of the invention. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the detection methods taught by Londos to detect the sequences of the instantly claimed invention as Londos teaches that such methods can be used to detect nucleic acids in a test sample. Once the nucleic acids were detected the information could be used for further characterization of the nucleic acids, such as chromosomal location, linkage analysis, disease association and other various experimental tests. Therefore, since the nucleic acids were known in the art at the time the invention was made, it would have been obvious to further evaluate the sequences and characterize the material itself.

Conclusion

13. No claims allowable.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of formal matters can be directed to the patent analyst, Chantae Dessau, whose telephone number is (703) 605-1237.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg

Jeanine Goldberg
February 13, 2003

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
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